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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,193	12/12/2001	Mai Huong Dang	52200.8010	5901

22918 7590 04/29/2005

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EXAMINER	
PADGETT, MARIANNE L	

ART UNIT	PAPER NUMBER
1762	

DATE MAILED: 04/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/017,193	DANG ET AL.	
	Examiner	Art Unit	
	Marianne L. Padgett	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *11,16-19,27 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,13-15,20-26 and 29-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 14, 2005 has been entered.

2. Claims 7 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 7, while percentages themselves do not have units, it is necessary to know what units were used when calculating the percentage for it to be meaningful. So, is the "less than ten percent..." based on moles, volume, flow rates, or what?

In claim 31, if homo = same, so homo-functional means all the same, what is there to alternate? Section D, pages 11 and 12 in the specification does not define its meaning, hence clarification is needed.

3. On page 8 of the specification, the examiner notes that "at or near atmospheric pressure" is defined to be from about 0.1 atm (76 torr) to about 2 atm. The amended phrasing in claim 1, requiring "substantially at atmosphere pressure", while overlapping with the original disclosure on page 8, would be considered much narrower, where substantially will be considered to have essentially the same meaning as would 'about'. The above-recited disclosure is considered to suggest the new pressure range; hence it is supported, with the same paragraph supporting the chamber limitation.

While the page 10 disclosure of the equivalent of claim 1, step (b) does not exclude using plasma for the "under conditions effective to convert...", neither does it suggest the use thereof, hence this negative amendment will not be considered new matter.

As noted in the advisory action (mailed 11/8/2004), the rejection over Beumer et al is removed, as they employ plasma for what use to, before amending, read on both plasma treating and functionalizing.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-9, 21-26 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikada et al (4,743,258), as discussed in section 8 of the 7/18/2003 action, and section 7 of the 4/15/2004 action; in view of Yializis et al (6,118,218) or Krause et al (5,500,257).

Note for the claims as amend 10/15/2004 that the steps of Ex. 2 in Ikada may be considered relevant as follows: (1) step (a) plasma exposing in a chamber at about 1 atm is read on by the corona discharge process in air, with use of a chamber neither disclosed nor excluded; (2) the exposure to gas or liquid effective to convent active species of step (b) may be considered to occur after the corona discharge due to normal exposure to air before the immersion step, when any activated sites that are radicals, etc., may react with components of air, such as O_2, etc., to further functionalize the surface (note claim 25 now clearly dependent from this step includes air as species and is consistent with such a sequence) or the aqueous solution (contains water) in which it is immersed can be said to read on either or both steps (b) and/or (c), where graft polymerization occurs on the activated surface, which may alternately be considered functionalized by the air to which is was exposed after corona activation. The very broad and general nature of applicant's limitations makes such interpretation possible.

With respect to the use of a chamber for the atmospheric pressure plasma, corona discharge plasmas, as used by Ikeda et al and previously discussed, are old and well known to be used either with or without a chamber depending on gases employed, potential for contamination of either the product or the surrounding environment, as was substantiated by Krause et al (col. 5, lines 7-34), hence would have been obvious to employ either configuration in Ikeda et al depending on those considerations.

Alternately, Yializis et al teach an atmospheric plasma treater, useful for treatment of films and surfaces, such as polymer ones used by Ikada, which is taught to be an improvement on prior art plasma and corona discharge processes, and as illustrated in Figures 1, 4-8 the electrodes and plasma space are always enclosed, whether the plasma treater is open at input and out put of the continuous substrate to atmosphere as in 1 and 4 or has fully enclosed spaces as schematics of 6 or 7 might imply. Yializis et al

teach their process provides a uniform treatment superior to corona or low temperature plasma or atmospheric pressure glow discharge, and is useful for gases, such as He, Ar, alone or mixed with N_2, O_2, air, CO_2, CH_4, C_2H_2, ammonia, etc. Examples 1-3 treat polypropylene, PET or polyethylene with various gas mixtures to produce favorably changes in surface energy, i.e. activation, taught to be useful in functionalization of polymer films for controlled wettability and adhesion. See the abstract; col. 1, lines 21-55+; col. 2, lines 6-65+; col. 5, lines 5-34, esp. 25-34; col. 6, lines 40-67 and examples.

Given the teachings in Ikada et al of using either low temperature plasma or corona discharge (col. 2, lines 64-66), as well as the specific corona examples 2, it would have been obvious to one of ordinary skill in the art to employ the technique or configuration therefore as disclosed by Yializis et al, because of its taught superior uniformity as compared to other configurations and because if its analogous use on types of substrates and gases, entirely overlapping with Ex. 2 and extensively with other options.

6. Claims 1-2, 5, 7, 25-26 and 29-30 (31) are rejected under 35 U.S.C. 103(a) as being unpatentable over Gudimenko et al (2003/0021996 A1), in view of Yializis et al (discussed above).

Gudimenko et al employs corona discharge processes for surface activation, and in paragraph [0027], the process is in air at atmospheric pressures as is well established, noting that the corona discharge treatment that causes the active species to impinge on the substrate and "initiate free radical reaction sequences creating functional groups on the surface" reads on applicants' steps (a) and (b), since the creation of functional groups is dependent on the activated sites already created, not the continuing discharge *per se*, hence will continue after the discharge until all remaining activated sites are functionalized. Further note that this substantiates above assertions for the process of Ikada et al in their Ex. 2. Note in claim 7, besides having an indefinite quantity due to undefined basis for the percentage, air may be considered to be a carrier for water vapor or various organic contaminants, and there is no other limit in the claimed range.

After activation and formation of functional groups with reactive hydrogen (-COOH, -OOH and -OH) on polymer substrates, Gudimenko et al teach surface silylation, where a silylating agent in either vapor or liquid form is reacted with the functional groups to replace the H with Si- containing groups, reading on either step (b) or (c), depending on whether or not the initial H-functionalization is completed during or after the corona plasma activation step. See the abstract; [0017-0020] noting the silylation may use water to proceed by a condensation reaction; [0024-27] and [0061] for activation; [0028-31] and [0057] for silylation; [0032] for uses including biomedical; and Ex. 1-16 on pages 5-7, where corona discharge, presumably in air as no gas is given, is used with various polymeric substrates. The silylation agent may be monofunctional or polyfunctional [0033], where [0042+] provides examples with agents that can be said to have N-Si-N or CH_3-Si-CH_3 or N-Si-CH_2-CH_2-Si-N backbones. Note the last has 2C in a row, and all contain heteroatoms. Not being sure what an alternate homofunctional molecule is, whether its taught or not in Gudimenko et al, cannot be determined (why claim 31 is in parenthesis in the above claim listing).

Gudimenko et al does not teach whether or not their corona activation plasma is in a chamber or not, but the activation technique and apparatus of Yializis et al (discussed above in section 5) would have been obvious for the same reasons set forth above.

7. Claims 1-2, 5-7 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Brien (6,709,718 B2), in view of Yializis et al, or visa versa.

O'Brien teaches atmosphere plasma treating porous polymeric materials, such as various polyolefin's, that may contain fluoropolymers. O'Brien specifically teaches atmospheric plasma treatments as taught in Yializis et al (218) as appropriate and plasma gases of O_2, N_2, air, CO_2 used alone or mixed with an inert gas, such as Ar or He. While O'Brien does not teach any proportions for when reactive gases are mixed with inert, Yializis et al does for examples of polypropylene, PET or polyethylene treated with He+ O_2, in Examples 1, 2 & 3, plus Tables 3, 6 and 9, respectively, where the

examples with 30 cc/min O_2 or less for 300 cc/min He, which correspond to 10% or less as calculated using volumetric flow rates, and produce useful surface energies; hence given O'Brien's suggestion to use Yializis et al plasma treatment as a basis, such mixture proportions would have bee obvious to apply to the generic teaching of gas mixtures in O'Brien, as would the use of the structures or chambers of Yializis et al, as they are essentially suggested, with no specific structures illustrated in O'Brien. See Abstract; col. 1, lines 5-20 and 33-38; col. 3, lines 4-18+; col. 4, lines 54-65; col. 6, lines 6-67+, especially 25-30 and 59-64. Example 1 on col. 7, makes a particular tri-layer porous polyethylene based sheet, which Ex. 2, treats with a 100% O_2 – plasma, then Ex. 3 treats this plasma activated polymer with water, which may be considered to read on contacting with liquid water and converting to a new functional group due to the interaction with the H_2O.

8. Claims 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by Kunz et al (6,733,847 B2).

Claims 7 & 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kunz et al.

Kunz et al teach treating various substrates, including many types of polymers (polyolefins, halogenated, etc.), that may have various forms, such as films, molded, extended, fibers, felts, woven fabrics, etc. (col. 3, line 42- col. 6, line 67). The first step may be subjecting the substrate to plasma or glow discharge at atmospheric pressure, where the gas may be a mixture of inert gas with reactive gases, such as N_2, O_2 or H_2O, with use of a closed system when air is to be excluded or if the apparatus is open, then flowing a sufficiently large amount of inert gas, which options are considered to read on applicant's various chamber and semi confined limitations. The next step after the discharge is discontinued, is applying as vapor or in solution, an electron- or H-donor to react with the free radical formed on the surface, that may be exemplified by amines. Thereafter, a further material (coating) may be applied or the work stored. See the Abstract; col. 2, line 30- col. 3, line 19; col. 7, line 13-25+; col. 9, line 51- col. 10, line 18; and col. 17, line 43- col. 18, line 36. While specific mixes of gas preparation for the corona

option are not taught, it would have been obvious to one of ordinary skill in the art to determine desirable proportion depending on specific materials being treated and required degree of surface functionalization for the particular end use.

Kunz et al does not disclose any particular solvents to use when solutions are being applied to functionalize the activated surface, however as many of the e^- or H- donors (Amines) are polar molecules, use of polar solvents, such as water, would have been an obvious option due to known solubility, thus obvious to employ due to expected effectiveness. Note as claimed the specifically listed gas or liquid does not have to be what is supplying the functional group; it just must supply the effective conditions.

9. Applicant's amendment has partly differentiated the present claims from the 6,159,531 patent, which requires both the cleaning (activation) and all of the "functionalizing" to be preformed using plasma, as it is the "plasma-deposited layer having functional groups", however active species formed on the surface by the plasma does not exclude those species being functional groups, since whether you call them "active species" or "stable functional groups", the reactive sites formed on the surface include those still able and optionally required to further react. So with the broad generic language employed in the present claims, the cleaning and plasma-deposited functional groups of claim 1 of (531) read on the formation of desired density of active species on the substrate by plasma in present amended claim 1 step (a). The subjecting the plasma-deposited layer to a wet chemical treatment to form bonds to create multifunctional liners/spaces via covalent bonds is a form of functionalization of active sites, thus reading on present claim 1, step (b). As step (c) is optional, it need not be considered.

10. Claims 1-10, 12, 21-23, 26 and 29-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 and 11-17 of U.S. Patent No. 6,159,531 (Dang et al), in view of Yializis et al, and further in view of Ikeda et al (258) in claims 3-6.

The claims as presently written differ by the patent's claims being more narrowly directed to a specific end use (medical devices) with the independent patent claim requiring more specific results at

each stage than the present application, but for these issues, the more generic present claims encompasses the more specific patent claims, hence are considered obvious variations on a range, especially considering that Ikada et al shows analogous processes with enduse in medical devices, as well as the above comments on meaning in section 9.

As amended the present claims require specific use of an atmospheric plasma, that is formed in a chamber, while the overlapping claims call for a generic RF plasma with no pressure or chamber constraints. Yializis et al, discussed above, teach an atmospheric pressure plasma, advantageous over conventional glow discharge at lower and atmospheric pressure and over corona discharge plasmas, useful for surface treatments as claimed and in Ikada, hence it would have been obvious to use the plasma that produces a superiorly uniform treatment in the generic (531) patented plasma process for its taught advantages, noting that Yializis et al's figures show use of RF power, so it is further consistent therewith.

While the patent does not claim specific surface densities of bioactive or compatible agents, it would have been obvious to one of ordinary skill to adjust the degree of their treatments depending on the desired concentrations in the resultant product and end use, hence lacking any broad specific significance to the generic limitations, such is considered routine optimization.

The patent does not claim specific shapes or morphologies to be treated, however Ikeda et al, discussed above shows the need and desirability to perform analogous treatments on tubular porous substrates as claimed, hence it would have been obvious to employ such substrates in the (531) patent process, as they have been demonstrated to be a type of medical device needing such treatments.

11. Claims 13-15 and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 & 11-17 of U.S. Patent No. 6,159,531 in view of Yializis et al, in view of Ikada et al ('258), as applied above in section 10, and further in view of Valentini (6,428,579 B1) or Clapper (5,744,515), discussed in section 6 of the action mailed 7/18/2003.

While the patent claims, specifically 3, specify cell-adhesion agents, they do not enumerate specific ones as in claims 13-15, however, Valentini or Clapper teach claimed bioactive molecules for bonding proteins or cell attachments, such as proteins, collegian, fibronectin and laimin in the former, and fibronectin, P- or N-cadherin in the latter, hence as these specific species were known for use in the generic function as a cell adhesion agent, it would have been obvious to employ them in the ('531) process for their know and intended function, as suggested by these ternary references.

12. Claims 1-5, 7-10, 12, 20-24, 26 and 29-30 (31) are rejected under 35 U.S.C. 103(a) as being unpatentable over Subramanian (5,643,580) in view of Yializis et al.

Subramanian ('580) teach plasma treating a surface to functionalize it, where that surface may be part of medical device, such as a catheter, vascular stents or various blood transfer devices, hence includes tubular substrates with lumen as well as plastic surfaces. The plasma is used to create reactive groups, such as hydroxyl or carboxyl or amine, on the surface via use of gas mixtures, such as CH_4/O_2 or H_2O/O_2 or CH_4/NH_3, where it is taught that the reactive groups may also be introduced with an inert carrier, such as He or Ar, typically in a 3:1 ratio. The reactive groups are then functionalized with an amphipathic compound (i.e. multifunctional linker) and a bioactive agent, either simultaneously or in sequence (reads on either step 1(b) or 1(b)+1(c)), where bioactive agents may include antithrombogenic compounds (heparin) or polypeptides (amino-acid sequences) or antibiotics or growth factors, etc. See the abstract; summary, esp. col. 1, lines 20-56; col. 2, lines 44-60; col. 3, line 1- col. 4, line 35, esp. col. 3, line 4-30 for gases and reactive groups, lines 32-50 for step sequences and lines 52-64 for uses with col. 4 discussing substrates; col. 5, lines 1-29 for a particular example with reactive amine groups, 1-ethyl- 3-(3-dimethylaminopropyl) carbiodimide as a multifunctional group, then heparin as a biological surface modifying group.

Subramanian differs by not using an atmospheric pressure plasma, but as discussed above Yializis et al teach such a technique as desirable over the taught low pressure low temperature plasma of the

primary reference due to the economic advantages of not needing vacuum, but also the improved uniformity of their (Yializis et al) particular procedure, hence it would have been obvious to employ as an alternative to Subramanian's low pressure glow discharge, especially considering that it specifically suggests the same gases with potentially the same combination for activation/pretreatment of polymeric surfaces. Furthermore, while Subramanian does not teach the claimed less than 10% of whatever, Yializis et al show varying results of different gas mixtures on different polymers for various lengths of time, hence it would have been obvious to optimizes for particular gas, substrate, surface energy, etc., where Yializis et al suggest that probable claimed proportions would have been effective, thus they would have been obvious along with the atmospheric plasma. The primary reference also does not teach density ranges as claimed, but optimization for particular desired densities of active sites, hence resultant deposited material would also have been considered.

13. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Subramanian ('580) in view of Yializis et al as applied to claims 1-5, 7-10, 12, 20-24 and 29-31 above, and further in view of Valentini or Clapper.

While Subramanian does not elaborate on what is included by "growth factors" or protein options (col. 3, line 64), they consistently suggest that other bioactive agents than those they explicitly exemplify would be usefully deposited by their technique (col. 2, line 51-55; col. 3, line 63-64; col. 6, lines 22-33), hence these teachings are considered suggestive of employing other biological agents that may influence or encourage growth or protein binding. Therefore, given teachings of desirable bioactive coating materials for cell growth, as in Valentini or Clapper discussed above, they would have been obvious for reasons given immediately above, as well as those discussed in Section 11.

14. Applicant's arguments filed 1/14/05 & discussed above have been fully considered but they are not persuasive.

Applicant's arguments with respect to claims 1-10, 13-15, 20-26 and 29-31 have been considered but are moot in view of the new ground(s) of rejection.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne L. Padgett whose telephone number is (571) 272-1425. The examiner can normally be reached on about 8:30 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks, can be reached at (571) 272-1423. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M.L. Padgett/dh
April 18, 2005
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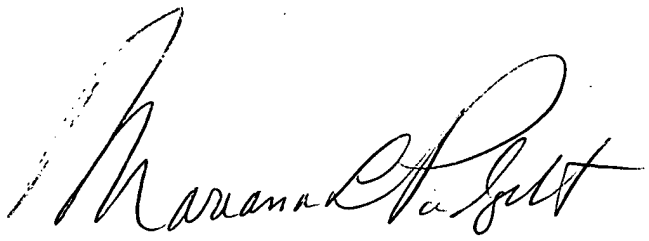
April 27, 2005



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PRIMARY EXAMINER